Healthcare Biotechnology

Summary

The size of the Indian biotechnology industry is estimated at $1.3 billion. This includes bio-healthcare, bio-agriculture, bio-industrial, bio-informatics, and contract and clinical research markets. Of the total market, healthcare biotechnology products account for 38 percent. The growing population, demand for quality diagnostics products and innovative drugs to combat diseases are leading to increased demand for biotechnology drugs and products. New types of diseases and demand for improved drugs are also leading to greater research and development (R&D) activities.

Market Overview

The size of the Indian biotechnology industry is estimated at $1.3 billion. It is expected to increase to $3.5 billion by the year 2008-09. These figures include several segments of the industry bio-healthcare, bio-agriculture, bio-industrial, bio-informatics, and contract and clinical research markets. The healthcare biotechnology products have a market share of approximately 38 percent. Over the past years this industry has witnessed a growth rate of 35-37 percent per annum. The main segments of healthcare biotechnology are recombinant therapeutics and bio drugs, vaccines, and diagnostics products.

Market Trends

In line with the global markets the Indian market for recombinant products is showing considerable growth. The Department of Biotechnology (DBT) has estimated the Indian market for recombinant therapeutics products at $90 million, which is growing at a rate of 30 percent per annum.

Product	Market Size	Growth Rate
Erythropoietin	$16.6 million	20 percent
G-CSF	$6 million	25-30 percent
FSH Market	$6 million	20 percent
Interferon	$12-13 million	30-40 percent
Insulin	$55 million	40 percent
Hepatitis B Vaccine	$22 million	NA
Streptokinase	$17 million	25 percent

Source: India Biotech Hand Book 2006, by BioSpectrum

Recombinant therapeutic products

Globally, 240 recombinant therapeutic products have been approved. The Government of India (GOI) has approved only 14 of these products for sale in India. These include human insulin, blood factor VIII, erythropoietin, granulocyte colony stimulating factor (G-CSF), alpha interferon, interferon b, GMCSF, streptokinase, basiliximab, follicle stimulating hormone (FSH), and hepatitis-B. Of these 14 GOI approved recombinant drugs, 7 are being locally manufactured while the rest are being imported. Sun Pharmaceutical and Torrent Pharmaceutical are into contract manufacturing of recombinant products for Eli Lilly and Novo Nordisk. Though several Indian companies are engaged in research and development of recombinant products, presently only 6 Indian companies are manufacturing them while 16 companies are importing and selling recombinant products in India.

There are seven brands of human insulin available in India. These include both Indian and foreign brands. Insulin is available in vial form in different strengths ranging from 40iu/ml to100 iu/ml. In November 2004, Biocon, a Bangalore based Indian company, launched a new generation of bio-insulin called Insugen. In August 2005, Eli Lilly India launched its insulin analog under the brand name of Humalog Mix 25-50. Indian companies like Wockhardt, Shantha Biotechnics and Intas Phramaceutical manufacture erythropoietin. Several other Indian companies have licensing agreements with the multi-national companies (MNCs) to market recombinant erythropoietin. Janssen Cilag CRF a division of Johnson & Johnson was amongst the first companies to successfully launch a biotechnology drug in India under the brand name Eprex. Hindustan Antibiotics has tied up with a U.S. company Elanex Pharmaceutical to market their product under the brand name Hemax.

Branded Biotech Drugs in India

Recombinant Brand	**Company**
Human Insulin	
Huminsulin	Eli Lily and Company India
Insugen	Biocon
NovoMix39 and NovoRapid	Novo Nordisk
Reconsulin	Shreyas Life Sciences
Wosulin	Wockhardt
Streptokinase	
Indikinase	Bharat Biotech
Shankinase	Shantha Biotechnics
STPase	Cadila Pharmaceuticals
Erythropoietin	
Ceriton	Ranbaxy
Epofit and Erykine	Intas Pharma
Eprex	J& J
Hemax	Hindustan Antibiotics
LG Espogen	LG Chemicals
Shanpoietin	Shantha Biotechnics
Vintor for Nephrology/Epofer for Haematinics	Emcure
Wepox	Wockhardt
Zyrop	Zdyus Biogen
Hepatitis B Vaccine	
Bevac	Biological E
Biovac B	Wockhardt
Engenix-B	GlaxoSmithKline India
Enivac HB	Panacea Biotec
Gene Vac-B	Serum Institute of India
LGEuvax B Inj	LG Chemicals
Revac B	Bharat Biotech
Shanvac B	Shantha Biotechnics

Human Growth Hormone	
Humatrope	Eli Lilly India
LG Eutropin Inj	LG Chemicals
Norditropin, NordiLet	Novo Nordisk
Saizen	Serum Institute of India
G-CSF	
Emgrast	Emcure
Grastim	Dr. Reddy's Labs
Neukine	Intas Pharma
Interferon alpha 2a	
LG Intermax alpha Inj	LG Chemicals
Interferon alpha 2b	
Intron A	Fulford India (Schering Plough)
Markferon	Glenmark Labs
Shanferon	Shantha Biotechnics
Zaveinex	Zdyus Biogen
Interferon beta 1a	
Avonex	Nicholas Piramal- Biogen
Blood Factor VIII	
FSH Gonal-F	Serum Institute of India Ltd.
LG Follimon Inj	LG Chemicals
Tissue Plasminogen Activator	German Remedies
Alpha Drotrecogin	
Xigris	Eli Lily and Company (India)

Source: India Biotech Hand Book 2006, by BioSpectrum

Though there are several Indian companies manufacturing recombinant human hepatitis B vaccine, multinational companies such as GlaxoSmith Kline and LG Chemical also market their brands of vaccine. Looking at the tough price competition, it is estimated that the market for hepatitis B vaccine will grow in terms of volume, but will decline in terms of value. There exist s demand for new vaccine for malaria, HIV, TB, rotavirus and cancer. The other vaccines in demand are typhoid, hepatitis C, and cholera.

There are several other biotechnology products available in India. Blood factor VII drugs that are sold by LG Chemicals and Serum Institute are made available to hemophilia patients through the Hemophilia Federation. Several Indian and foreign companies sell rDNA products.

Diagnostic

The in-vitro diagnostic (IVD) industry is experiencing rapid technological developments and is estimated at $285 million. The need for a highly accurate and wider test menu has resulted in the introduction of new test parameters. The majority of diagnostic laboratories were restricted to routine biochemistry tests due to the low level of automation. However, laboratories are trying to differentiate themselves by offering specialized tests such as drug screenings, extended lipid profile, therapeutic drug monitoring, molecular diagnostics for autoimmune disorders, cytogentics or disease-related abnormalities in chromosomes and hormones. This range is likely to increase to include cancer, HIV, tumor, and hepatitis marker tests. Today Indian labs offer comprehensive test menus of over 1500 tests. It is expected that the $17 billion Indian healthcare market will grow at rate of 13 percent per annum. The pathology market is currently 2.5 percent of the overall healthcare market. There are 40,000 independent pathological laboratories in the country and around 70 percent of treatment decisions are based on laboratory results. There are about 25 companies manufacturing diagnostic kits, and equipment and reagents.

Indian Disease Burden Estimations

The growing population, change in disease patterns, and demand for new medicines to combat these diseases are leading to increased demand for bio drug, vaccines and diagnostics products. The below table provides the estimated cases of diseases in 100,000.

Disease/Health Condition	2000-05	2015
Communicable Diseases, Maternal & Prenatal Conditions		
Tuberculosis	85	NA
HIV/AIDS	51	190
Diarrheal Disease episodes/yr	760	880
Malaria and other vector borne conditions	20.37	NA
Leprosy	3.67	Expected to be eliminated
MR/1000 births	63	53.14
Otitis Media	3.57	4.18
Maternal Mortality/100000 births	440	NA
Non-Communicable Conditions		
Cancers	8.07	9.99
Diabetes	310	460
Mental Health	650	800
Blindness	141.07	129.96
Cardiovascular Diseases	290	640
COPD and Asthma	290	640

Source: India Biotech Hand Book 2006, by BioSpectrum

Biotech Clusters

The central and state governments have been taking many initiatives to support the biotechnology industry through development of biotechnology parks, policy initiatives, and tax incentives. Governments are working towards developing cities for knowledge-based sectors like biotechnology, medical biosciences, and life sciences. It is estimated that India will have at least 20 biotech parks in the next few years. Currently four cities – Chennai, Hyderabad, Lucknow and Pune – have taken the lead in developing biotechnology-dedicated parks. Other states that have announced plans to develop biotechnology parks include Karnataka, Kerala, Tamil Nadu, Gujarat, Chandigarh, Haryana, Himachal Pradesh, Madhya Pradesh, Punjab, Rajasthan, Uttar Pradesh and Uttaranchal, Orissa and West Bengal.

The following are the existing biotechnology parks: The Shapoorji Pallonji Biotech Park in Andhra Pradesh is a public-private partnership between the state Government and Shapoorji Pallonji Incorporated. 20 companies both Indian and foreign have established their units in this Park, making an investment of $85-90 million. Sigma Aldrich from U.S. and Altanta AG from Germany are planning to establish facilities in this Park, while Randox Laboratories from U.K. is establishing a diagnostic kits manufacturing unit in Bangalore.

Another park in Andhra Pradesh is the ICICI Knowledge Park. This park is focused on facilitating business-driven research and development. The park is spread over 200 acres and about 13-15 companies, both Indian and foreign, are currently operating there.

The Ticel Bio Park is located near Chennai. The Tamil Nadu Industrial Development Corporation in technical collaboration from Cornell University have promoted this park.

Key Suppliers
The major suppliers of biotechnology products include U.S., European and Indian companies. Some of the Indian companies manufacturing healthcare biotechnology products include Bharat Biotech International, Bharat Immunological and Biological, Bharat Serum, Biocon, Dr Reddy's, Haffkine Bio-Pharma, Indian Immunological, Krebs Biochemical, Panacea Biotec, Serum Institute of India, Shantha Biotechnics, Wockhardt, Ranbaxy Laboratories, Organon India, Kee Pharma, Emcure Pharmaceuticals, Glenmark Labs, Lupin Labs, Nicholas Piramal, Intas Pharma, Hindustan Antibiotics and Shreyas Life Sciences.

Foreign companies in India include Eli Lilly, Novadisk, Johnson & Johnson, Fulford India, Wyeth Lederle, Glaxo SmithKline, Aventis Pharma, Pifzer and LG Chemical.

Prospective Buyers
Most of the bio drugs and diagnostic products are for the government and private sector hospitals and patients. The second group of buyers of biotechnology products and bio molecules are the research institutes and pharmaceutical companies.

The emerging trend of corporate players establishing diagnostic centers in small towns and rural areas will provide opportunities for the import of automated systems and imported reagents. Currently, there are only a few large national players in diagnostics care segment including SRL Ranbaxy, Max Healthcare, Dr. Lal's Laboratory, Metropolis, Thyrocare, Fortis Healthcare and Apollo Clinics. The large private hospitals are upgrading their facilities and/or adding new facilities.

Following are some of the major hospitals:

- Fortis Healthcare Limited (http://www.fortishealthcare.com/index.html)
- The Apollo Hospital group (http://www.apollohospitals.com/)
- Sri Satya Sai Institute of Medical Science (http://www.sathyasai.org/saihealth/bnglrhosp.htm)
- Sri Ramachandra Medical College and Hospital (http://www.hostindia.com/srmc/)
- Breach Candy Hospital Trust (http://www.breachcandyhospital.org/home.htm)
- Jaslok Hospital and Research Center (http://www.jaslokhospital.net/)
- P.D. Hinduja National Hospital & Research Center (http://www.hindujahospital.com/)
- Wockhartd Hospital and Heart Institute (http://www.whhi.com/)
- Christian Medical College Hospital (http://cmch-vellore.edu/main.asp)

Following are some of the major research institutes:

- Central Drug Research Institute (http://www.cdriindia.org)
- Central for Cellular and Molecular Biology (http://www.ccmb.res.in)
- Centre for DNA Fingerprinting and Diagnostics (http://www.cdfd.org.in)
- Indian Institute of Science (http://www.iisc.ernet.in)
- Industrial Toxicology Research Centre (http://www.itrcindia.org)
- Institute of Bioresources and Sustainable Development (http://www.ibsd-imphal.nic.in)
- International Center for Genetic Engineering and Biotechnology (http://www.icgeb.org)
- Institute of Genomics and Integrative Biology (http://www.igib.res.in)

- National Brain Research Centre (http://www.nbrc.ac.in)
- National Centre for Biological Sciences (http://www.ncbs.res.in)
- National Centre for Cell Sciences (http://www.nccs.res.in)
- National Environmental Engineering Research Institute (http://www.neeri.nic.in)
- National Institute of Immunology (http://www.nii.res.in)
- National Chemical Laboratory (http://www.nci-india.org)

Market Entry

The Government of India's import policy allows import of biotechnology products under the "Open General" category of the import regulations, which does not require any government approval. The Government has simplified import procedures and has been reducing the import duties to encourage import of capital goods and raw materials.

Price, quality and after-sales service support are major factors in purchase decisions. A letter of credit is the usual payment mechanism for imports. Importers are required to find foreign exchange from their export earnings, or to buy foreign exchange from government approved foreign exchange dealers. U.S. manufacturers and exporters are advised to identify competent agents and distributors who offer a strong sales and after-sales service support.

Market Issue

Though there is great potential for imports and investments in the field of Indian healthcare biotechnology, the industry faces several challenges. The first of these is inadequate intellectual property (IP) protection. In 2005 India committed to product patent by amending its patent laws, however, foreign companies are apprehensive about IP protection. Hence, the industry is primarily led by few entrepreneurs and fragmented government supported research. Strong IP protection through proper enforcement is imperative for product development. Second, most of the healthcare spending is "out of pocket spending " as a result new innovative drugs that are expensive and not affordable by Indian patients are not sold in India. This has kept large global biotechnology companies from entering the Indian market. With increasing health insurance coverage the market scenario is expected to change. Third, the industry faces a shortage of skilled biotechnology professionals. Until recently, most biotech research was conducted by government institutes in collaboration with the private sector. Now several education institutes both schools and colleges have introduced biotechnology courses.

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Upcoming Trade Shows

- Bangalore Bio 2006 is a major biotechnology trade exhibition held in India. For details please visit the website http://www.bangalorebio.in/
- Bio Asia is another major biotechnology trade exhibition to be held 2007. For details please visit the website http://www.hitex.co.in/
- HospiMedica India is the health care products trade exhibition held in India. For details please visit the website http://www.hospimedica-india.com/ .

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